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REMARKS

Claims 301, 303-310, 322-333 are pending in the application. Attached hereto is a marked-up version titled, "Version with Markings To Show Changes Made".

Claim Rejection 35 U.S.C. § 112, paragraph 2

By this Reply claims 301, 326, 329 and 331 have been amended to more particularly point out and distinctly claim the current subject matter. Claim 329 has been amended to more distinctly claim a method in which non-conforming solids are utilized to increase the antimicrobial concentration of a subsequent fermentation broth. Thus the non-conforming solids are introduced into a subsequent fermentation broth as cited previously in Claim 329 to increase the antimicrobial combating capability of the subsequent method.

With regard to claims 303-306, the antimicrobial concentration of the granules are what is being claimed . The claim schedule 303-306 is believed to adequately define the invention for which the Applicant seeks protection. If the Office is attempting to reject the claims under 35 U.S.C. § 112, paragraph 1, support for the claim limitations of claims 303-308 may be found at page 16, lines 11-14. Withdrawal of the rejection is respectfully requested.

Applicant respectfully requests the Office clarify exactly what language the Office is objecting to with respect to Claims 307 and 308, such that the Applicant may amend or offer arguments rebutting the Office's position. Removal of the rejection is respectfully requested.

Regarding claims 309 and 310, it is believed that the claim limitations of mesh size are sufficiently defined. Specifically, Claim 309 further limits the method of Claim 301 to employing granules of (approximately) between 80 mesh (180 μm) to 10 mesh (2 millimeters). While, Claim 310 further limits the method of Claim 301 to the utilization of

granules of at least /approximately 10 mesh (2 millimeters). Support for the limitations of Claims 309 and 310 are found at page 29, lines 22-29. Particle size as recited in Claim 301 refers to the physical size of the granules. Withdrawal of the rejection is respectfully requested.

Applicant respectfully requests the Office clarify exactly what language the Office is objecting to with respect to Claims 322-325 and 327-328, and 330-333 such that the Applicant may amend or offer arguments rebutting the Office's position. Removal of the rejection is respectfully requested.

Removal of the pending rejection to Claims 301, 303-310, and 322-333 under 35 U.S.C. §112, second paragraph is respectfully requested and allowance solicited.

Claim Rejection 35 U.S.C. § 102

35 U.S.C. § 102(b)

Claims 301, 303-308 stand rejected under 35 U.S.C. §102(b) as being anticipated over King (United States Patent Number 5,266,347), hereinafter *King*. Applicant respectfully disagrees.

> [A]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, *arranged as in the claim.*" *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1982) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1984)) (emphasis added).

Regarding Claims 301, 303-308, the present methods are directed generally to providing an edible medicated supplement for animals. The method of Claim 301 teaches the steps of orally administering a sufficient amount of edible supplement for inducing a prophylactic or therapeutic effect in animals, wherein the supplement is generated by the steps. Claims 301 and 303-308 are specifically directed to the active concentration of the granules and not to a concentration within a feed mix as suggested. (Claims 307 and 308

include the additional limitation of specified amounts moisture content.) Claim 301, in particular, claims a medicated (solid) supplement having an antimicrobial concentration of 10g/lb. In contrast, *King* teaches the addition of antibiotic biomass for preventing fungal contamination in feed prior to consumption. *King*, Col. 4, lines 14-19. emphasis added. This is not the present invention. Specifically, *King* does not teach administering the composition to achieve a desired prophylactic or therapeutic effect in animals. *King* teaches a nonviable antibiotic biomass. *King*, Abstract. Thus, the feed composition of *King* is specifically not able to generate a prophylactic or therapeutic effect for an animal consuming the material as recited in Claims 301 and 303-308.

With regard to the Office's recitation of "The composition can include soybean meal or flour, or fishmeal...thus, would include the instant claim amount of oil. Rice hulls ...or limestone may be used". Applicant respectfully requests the Office clarify exactly what claims the Office is rejecting such that the Applicant may amend or offer arguments rebutting the Office's position.

Claims 307 and 308 are believed to be allowable based on their dependence from claim 301. Applicant will not burden the record further.

Removal of the pending rejection to Claims 301, 303-308, under 35 U.S.C. §102(b) is respectfully requested and allowance solicited.

Claims 301, 303-307, 309, 310, 322-333 (appear) to stand rejected under 35 U.S.C. §102(b) as being anticipated over Forbes et al., (sic) Forberg (DD 138273), hereinafter *Forberg.* Applicant respectfully disagrees. References in this Reply refer to the translated summary provided.

> As the Examiner is aware, the Office should "ordinarily should reject each claim on all valid grounds available." *M.P.E.P. §707.07(g)* Further, "[w]here

a major technical rejection is proper, it should be stated with a full development of reasons..." *Id.*

The presently claimed invention relates to a method for combating microbial infection in animals, which includes the steps of (with respect to Claim 301) culturing an organism in a fermentation broth, reducing the broth to obtain fermentation solids including an antibiotic, drying the solid and granulating the solid which are substantially of uniform size, and have an antimicrobial concentration of at least 10 g/lb. Forberg fails to describe the present invention. As the Federal Circuit noted, "An *anticipating* reference must describe the patented subject matter *with sufficient clarity and detail* to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of invention." *ATD Corp.v. Lydall, Inc.,* 48 USPQ.2d 1321,1328 (Fed. Cir. 1998) citing *In re Spada,* 15 USPQ.2d 1655, 1657 (Fed. Cir. 1990). emphasis added. Thus, in order to be an anticipating reference the art must teach all the limitations of the invention sufficiently to allow recognition. This reference does not teach the presently claimed methods for combating microbial infection including the steps defining the invention. Moreover, *Forberg* fails to teach the limitation of substantially uniform granules as claimed.

With respect to the Offices assertion "added antibiotic is admixed", *Forberg* teaches admixing the agent in the form of the free base, a salt or a derivative. This is not the present invention. Adding purified material may be costly, the present invention and specifically claim 322 recites "adding an additional quantity of fermentation solid" to the broth to increase antibiotic activity. Thus, not only is the concentration raised but cost is minimized. Removal of the pending rejection is respectfully requested and allowance solicited.

Regarding the Office's assertion that the granule size "would be of the instant size, in order to provide acceptable taste (p.2) and dust free (p.3, top) protection". Applicant respectfully requests the Office clarify how the size of particles influences the cited factors such that the

Applicant may amend or offer arguments rebutting the Office's position. With respect to the cited particle sizes, such as in claims 309, 310, *Forberg* fails to teach particle size limitations.

Removal of the pending rejection to Claims 301, 303-307, 309, 310, 322-333 under 35 U.S.C. §102(b) is respectfully requested and allowance solicited.

Claim Rejection 35 U.S.C. § 103

35 U.S.C. § 103(a)

Claims 301, 303-307, 309, 310, 322-333 stand rejected either as anticipated under 35 U.S.C. §102(b) or as obvious under 35 U.S.C. §103(a) over Forbes et al., (sic) Forberg, (DD 138273) hereinafter *Forberg* . The rejections is respectfully traversed.

As the Examiner is aware, "In proceeding before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art..." *In re Fritch*, 972 F.2d 1260, 24 USPQ.2d 1780, 1783 (Fed. Cir. 1992). Specifically, Claims 301, 322, and 329 claim methods of combating microbial infections in animals. Claim 322 recites a method wherein additional fementation solid is added. Claim 329 includes the limitation of screening the granulated solid. As cited previously, *Forberg* fails to teach these limitations.

When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to: (A) the claimed invention must be considered as a whole; (B) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) reasonable expectation of success is the standard with which obviousness is determined. *See MPEP §*

2141 and Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 220 USPQ 182, 187 n.5 (Fed. Cir. 1986).

Moreover, to establish a *prima facie* case of obviousness "it is necessary to ascertain whether the prior art teachings would appear to be sufficient to one of ordinary skill in the art to suggest making the claimed substitution or other modification." *In re Lalu*, 747 F.2d 703, 223 USPQ 1257, 1258 (Fed. Cir. 1984). This is not the case with *Forberg*. *Forberg* merely adds additional (purified) antibiotics. This is not the present invention. Rather, the present invention (Claim 322) utilizes fermentation solids to generate a higher concentration. Specifically, with regard to Claim 322 the use of purified material teaches away from the present invention because the addition of purified material would result in a higher cost product. *Application*, Page 2, lines 15-19. Whereas the method as claimed in Claim 322 recites adding additional fermentation solids to the broth. As the Federal Circuit has noted, "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." *M.P.E.P. 2131.02, citing W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Further, the passage cited by the Office in *Forberg* refers to biomass material added "for the improvement of the drying process" as well for the materials fodder (nutritive) property and not for increasing the antimicrobial concentration as claimed in Claim 322. *Forberg*, Page 6. Removal of the pending rejection is respectfully requested and allowance solicited.

Claims 301, 303-310, 322-333 stand rejected under 35 U.S.C. 103(a) as obvious over Forbes et al. (sic) Forberg (DD 138273) in view of Klothen (United States Patent Number 4,447,421) hereinafter *Forberg* and *Klothen*, respectively. Applicant respectfully disagrees.

Forberg teaches the addition pure antibiotic material in the form of the pure base, of a slat (salt) or of a derivative. *Forberg*, page 4. As noted previously, this is not the present invention. Specifically, Claim 322 recites adding additional fermentation solids to the broth. *Klothen* does not correct the deficiencies of the *Forberg* reference because *Klothen* merely teaches a process of standardizing the potency of feed supplements. *Klothen*, Abstract. In addition, while the present invention is directed (generally) to a method of combating microbial infections through the implemenation of uncompacted granularized high concentration granules. *Klothen* teachs compacting the material. *Klothen*, Col. 3, lines 9-16. Thus, not only does *Klothen* fail teach the present invention, but in addition *Klothen* teaches away from "uncompacted granules" as recited in Claims 301, 322. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. .... It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Oetiker*, 977 F.2d 1443, 24 USPQ 2d 1443 (Fed. Cir. 1992) *quoting In re Fine*, 837 F.2d 1071, 1075, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988).

Furthermore, with respect to Claims 303-306, 327-328, and 332-333, *Klothen* fails to teach the claimed antimicrobial concentrations range from about 200g/lb to about 300g/lb. Removal of the pending rejection to Claims 301, 303-310, and 322-333 is respectfully requested and allowance solicited.

Marked-Up Version of Amendment

Attached hereto is a marked-up version of the changes made to the specification and claims by the present amendment. The attached marked-up version is captioned "***VERSION WITH MARKINGS TO SHOW CHANGES MADE***".

CONCLUSIONS

In light of the forgoing, reconsideration and allowance of the claims is earnestly solicited.

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Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please amend the claims as follows:

301. (Twice Amended) A method of combating microbial infection in animals comprising orally administering to said animals a prophylactic or therapeutic amount of an animal comestible composition comprising a medicated supplement prepared by culturing an organism producing an antibiotic in a fermentation medium to produce a fermentation broth; reducing said fermentation broth to obtain fermentation solids comprising said antibiotic; drying said filtration solids to produce a dry solid; and granulating said dry solid to produce granulated fermentation solids comprising uncompacted granules having a substantially uniform particle size, wherein the granules have an antimicrobial concentration [sufficient to treat an animal] of at least 10 g/lb.

326. (Amended) The method as described in claim 322, wherein the granules have an antimicrobial concentration [sufficient to treat an animal] of at least 10 g/lb.

329. (Amended) A method of combating microbial infection in animals comprising orally administering to said animals a prophylactic or therapeutic amount of an animal comestible composition comprising a medicated supplement prepared by culturing an organism producing an antibiotic in a first fermentation medium to produce a fermentation broth; reducing said fermentation broth to obtain fermentation solids comprising said antibiotic; drying said filtration solids to produce a dry solid; granulating said dry solid to produce granulated fermentation solids; screening the granulated fermentation solids to arrive at a first group of granulated solids corresponding to a desired mesh size and a second group of solids which do not correspond with the desired mesh size; and adding the second group of

solids to a second, subsequent, fermentation broth having an organism producing an antibiotic in a second fermentation medium for increasing the antimicrobial concentration of a subsequent animal comestible composition, for combating microbial infection in animals.

331. (Amended) The method as described in claim 329, wherein the granules have an antimicrobial concentration [sufficient to treat an animal] of at least 10 g/lb.